The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper No. 168

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Junior Party, (Patent 5,244,657),

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Senior Party (Application 08/448,727).

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference No. 104,147

DECISION ON JOINT MOTIONS 1 AND 2

Lorin, Administrative Patent Judge.

The parties have filed the following papers:

- "Joint Motion 1 Pursuant To 37 CFR 1.645(b);" Paper No. 164;
- "Joint Motion 2 Pursuant To 37 CFR 1.633(b);" Paper No. 165; and,
- Joint Exhibits 1-3; Paper No. 166.

Joint Motion 1 is a joint request for entry of belated Joint Motion 2 which seeks a

judgment of no interference-in-fact pursuant to 37 CFR §1.633(b). Undersigned agrees that the construction of Burnette claim 9 attributed to it by the count construction given in the Decision on Motions (Paper No. 144) puts a different posture on the interference, in light of which, the parties should be given a new opportunity to reconsider their position. Accordingly, Joint Motion 1 is GRANTED and Joint Motion 2 is thereby considered.

Joint Motion 2 is a joint motion for judgment filed under 37 CFR §1.633(b) on the ground that there is no interference-in-fact.

As the parties have observed, in the Decision on Motions (Paper No. 144, pp. 7-14) undersigned construed the count broadly. That is to say, undersigned declined the parties' motions to substitute the count because the motions were premised on too narrow an interpretation of the scope of the count. Undersigned explained that based both a plain reading of the count and a reading fo the count in light of the originating disclosure (i.e., Burnette's application in interference), "the broadest reasonable interpretation of the subject matter of the count is that the analog defined thereby is limited not by the context within which the S1 subunit analog finds itself or the number or type of modifications to the amino acid sequence of the naturally-occurring S1 subunit in addition to a substitution at Arg⁹ but only to the extent that the resulting S1 analog is able to (a) elicit toxin-neutralizing levels of antibodies and (b) be substantially free of enzymatic activities associated with toxin reactogenicity" (p. 13). The parties do

¹ Count 1: A polypeptide analog of Bordetella pertussis toxin S1 subunit, said analog differing in amino acid sequence from that of naturally occurring S1 subunit by substitution of a different amino acid residue at arginine 9, wherein the analog has a biological activity which (a) can elicit toxin neutralizing-levels of antibodies and (b) is substantially free of enzymatic activities associated with reactogenicity.

not dispute the construction given to the count as discussed in the Decision on Motions. Accordingly, that construction stands.

Furthermore, because the count and Burnette claim 9² are identical, the count construction given in the Decision on Motions applies equally to Burnette claim 9.

Accordingly, Burnette's claimed invention is similarly a genus; that means, Burnette claim 9 is <u>not</u> limited to

- the pertussis holotoxin;
- a single modification in the S1 subunit of the holotoxin; and
- wherein the single modification is the substitution of LYS⁹ for ARG⁹.

By contrast, Klein's claimed invention, represented by Klein's sole independent claim 1³, is a species. It is limited to

- the pertussis holotoxin, and
- a single modification in the S1 subunit of the holotoxin;
- wherein the single modification in the S1 subunit of the holotoxin is the substitution
 of LYS⁹ for ARG⁹.

These are the facts underlying the parties' Joint Motion 2.

37 CFR §1.601(n) sets forth the rule for determining whether there is an

² 9. A polypeptide analog of Bordetella pertussis toxin S1 subunit, said analog differing in amino acid sequence from that of naturally occurring S1 subunit by substitution of a different amino acid residue at arginine 9, wherein the analog has a biological activity which (a) can elicit toxin neutralizing-levels of antibodies and (b) is substantially free of enzymatic activities associated with reactogenicity.

³ 1. An immunoprotective genetically-detoxified mutant of pertussis holotoxin wherein a single amino acid in the S1 sub-unit in the native pertussis toxin is replaced, said single amino acid in the S1 sub-unit being ARG⁹ which is replaced by LYS⁹.

interference-in-fact; to put it succinctly, the test is whether a party and an opponent have claims designated to correspond the count that define the same patentable invention under 35 U.S.C. § 102 and § 103.

In light of the "two-way" test approved by the court (see Noelle v. Lederman, 335 F.3d 1343, 1351, 69 USPQ2d 1508, 1515 (Fed, Cir. 2004)) for determining "the same patentable invention," the issue here is whether Burnette's claimed invention anticipates or makes obvious Klein's claimed invention. On that issue, the parties agree that it does is not. There is no dispute that Klein's claimed species invention anticipates Burnette's claimed genus invention.

Undersigned agrees that the parties have made a persuasive case that Burnette's claimed invention does not anticipate or makes obvious Klein's claimed invention. The convincing elements of that case are 1) Klein's claims are limited to a complete holotoxin (pp. 9-10 of the motion) and 2) Klein's claims are limited to a single mutation at Arg⁹ (pp. 11-12 of the motion). It is quite apparent from reading Burnette's claims – especially in light of the construction of the count – that Burnette's claimed invention encompasses a myriad of forms comprising the S1 subunit and a large number and type of mutations. Even given that the S1 analog must (a) elicit toxinneutralizing levels of antibodies and (b) be substantially free of enzymatic activities associated with toxin reactogenicity, the potential number of combinations of forms and mutations would seem to be enormous. More importantly, however, there is nothing here that guides one to select Klein's singly-mutated holotoxin. For that reason, undersigned agrees that the parties' claimed inventions are not directed to the same

patentable invention.

Accordingly,

- "Joint Motion 1 Pursuant To 37 CFR § 1.645(b);" Paper No. 164; and,
- "Joint Motion 2 Pursuant To 37 CFR § 1.633(b);" Paper No. 165, are <u>GRANTED</u>.

Judgment consistent with the decision granting Joint Motion 2 filed pursuant to 37 CFR 1.633(b) for judgment of no interference-in-fact will now be rendered. See Paper No. 169.

HUBERT C. LORIN

Administrative Patent Judge

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